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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------------------|---------------|----------------------|---------------------|------------------|
| 10/572,853 | 02/09/2007 | Gen-Ichiro Soma | 80246(302741) | 9265 |
| 21874 | 7590 | 09/29/2009 | EXAMINER | |
| EDWARDS ANGELL PALMER & DODGE LLP | | | MI, QIUWEN | |
| P.O. BOX 55874 | | | ART UNIT | PAPER NUMBER |
| BOSTON, MA 02205 | | | 1655 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/572,853 | SOMA ET AL. | |
| | Examiner | Art Unit | |
| | QIUWEN MI | 1655 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 July 2009.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 12-14, 16-22, 26-29 and 33-38 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 12-14, 16-22, 26-29 and 33-38 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 3/22/06 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>6/24/09</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Applicant's amendment in the reply filed on 7/16/09 is acknowledged. Claims 1-11, 15, 23-25, and 30-32 are cancelled. Claims 12-14, 16-22, 26-29, and 33-38 are pending. **Claims 12-14, 16-22, 26-29, and 33-38 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

Claim Rejections –35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-14, 16-22, 26-29, and 33-38 remain rejected under 35 USC § 102 (b) as being anticipated by Soma et al (US 5,494,819), as evidenced by Inagawa et al (Homeostasis as regulated by activated macrophage. II. LPS of plant origin other than wheat flour and their concomitant bacteria, Chem. Pharm. Bull. 40 (4) 994-997, 1992)*.

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 4/16/09, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Soma et al teach three glucose-fermentative gram-negative small bacilli which produce lipopolysaccharide (LPSs) (col1, lines 12-15). The three bacterial according to the present invention were isolated from all kinds of wheat produced in any place and its processed goods

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(col 3, lines 10-16). Soma et al also teach in a 50 ml coning tube, there was charged 1.04 g of hard flour containing 1.09% of ash followed by addition of 20 ml of distilled water thereto to prepare a 50 mg/ml aqueous solution of wheat flour (thus a fermented edible plant extract). The solution was cultured in a water bath at 37°C for 0, 1, 2, 3, 4, 6, 8, 10, 12, 20, 24, and 45 hours (col 5, lines 46-55) (thus fermented, thus contains no component derived from an animal). Soma et al also teach the colony formation from and isolation of *Pantoea agglomerans* from aqueous solution of wheat flour (throughout the document). Thus the pure culture *Pantoea agglomerans* is the fermented extract from edible plant wheat, and therefore the fermented plant extract. Soma et al further teach a pure culture of *Pantoea agglomerans* (thus facultative anaerobic gram-negative bacterium, bacillus) which produces lipopolysaccharides (col 1, 7-13), and it may be used in food (thus a food containing the fermented plant extract, thus the limitation of claims 18 and 21 is met), drinks and feed (col 5, lines 10-15), it has excellent immunity-stimulating (thus the fermented plant extract has an immunopotentiation activity, thus the limitation of claim 17 is met), analgesic and antiwithdrawal effects show a high therapeutical range, and may be provided at a low cost and in a large amount (col 2, lines 50-55). At last, Soma et al teach any of the above preparations (thus a pharmaceutical, thus the limitation of claim 14 and 20 is met) including immunity stimulators may be produced conventionally. For example, in the conventional manner of preparing medicines (thus a composition, a pharmaceutical) or veterinary medicines, they may be supplied conventionally in the form of powders (thus a fermented plant extract powder, thus the limitation of claims 13,27, 34, 36, and 38 is met), granules, pills, tablets, troches, capsules, solutions, pastes, ointments, liniments, lotions (thus a bath agent containing the fermented plant

extract, thus the limitation of claims 19 and 22 is met), suppositories, injections, etc (col 5, lines 12-18).

As evidenced by Inagawa et al, lipopolysaccharide (LPS) of plant origin other than that of wheat flour was surveyed. Concomitant bacteria possibly extracting in root of farm products can be considered to contribute of LPS of plant origin. Some LPS were derived from concomitant bacteria which had probably come from root. Three predominant bacteria have been isolated and identified; *Pantoea agglomerans*, *Enterobacter cloacae* and *Serratia ficaria*. These LPSs were purified and their chemical compositions were examined (see Abstract). *Pantoea agglomerans* is the most remarkable, since it accounts for 40-70% of all living bacteria in wheat bran and wheat flour and is persistently isolated from all kinds of wheat flour produced in districts as different as, Canada, USA, Australia and Japan (page 996, 2nd column, last column). Inagawa et al also teach, *Pantoea agglomerans* is a species of gram-negative soil bacterial ubiquitously distributed, especially in cotton-seed and wheat, and contributes to the growth of plant by nitrogen fixation and also by release of phosphorus (page 997, 1st column, 1st paragraph) (thus lives in a symbiotic relationship exclusively with a plant).

Therefore, the aqueous solution of wheat flour culture in Soma et al inherently contains the symbiotic gram-negative soil bacterial *Pantoea agglomerans*, and “facultative anaerobic” is the intrinsic properties of the bacteria.

It is noted that since the cited reference teaches the claimed fermented plant extract, it is deemed that the fermented plant extract would inherently have macrophage activation ability even with the presence of polymyxin B (thus the limitation of claim 16 is met).

Therefore, the reference is deemed to anticipate the instant claim above.

*This reference is cited merely to relay an intrinsic property and is not used in the basis for rejection *per se*.

Applicant argues that “However, Soma USP 5,494,819 derives from a translation originally written in Japanese and the above section cited in the rejection contains some loosely translated words, thus the interpretation of the section is based on an imprecise translation, *rather than a logical determination about whether or not fermentation can occur under the disclosed conditions*. As will be shown below, logically fermentation cannot biologically occur and therefore the reference cannot legally anticipate the claimed invention. Therefore the rejection should be reconsidered in light of the explanation below” (page 7, 1st paragraph). Applicant also argues that “Soma discloses "was cultured...while shaking" in Col.5, lines 53-54. However, this process is explaining the operation in order to *isolate bacteria from wheat flour*. In fact, it is the *solution obtained from water and wheat flour, and bacteria cannot be cultured under this condition*. *Bacteria are cultured in standard agar culture media containing animal component which has been described later, then the colonies are observed*. When it is described "was cultured--while shaking" in Japanese language, it does not necessarily mean to "culture," but means to use a *concussion incubator*. The term "was cultured" was simply chosen in the process of translation work. *In view of this, Soma logically does not in fact disclose to ferment a material derived from an edible plant in culture media not containing animal-derived component*. The term "culture" is taken out of context of the actual disclosed medium present, which is not capable of "culturing" bacteria, as understood in English” (page 7, 2nd paragraph). Applicant further argues that “As a result, the disclosure referred to in the

reference is not properly interpreted as evidence of "culturing" because the fundamental ingredients" necessary for a culture (agar culture media) are not present, as indicated by Soma. Thus Soma, as evidenced by Inagawa still fails to anticipate the invention as now claimed, namely "simultaneously culturing said facultative anaerobic gram-negative bacterium in a medium containing no component derived from an animal." (page 7, 3rd paragraph).

This is not found persuasive. First of all, Soma et al explicitly teach "The solution was cultured in a water bath at 37°C for 0, 1, 2, 3, 4, 6, 8, 10, 12, 20, 24, and 45 hours". Secondly, bacteria could be cultured at 37°C water bath while shaking, and Applicant's understanding of culture as agar culture is very narrow. Thirdly, there is no recitation of agar culture in the claims. Thus, the reference is deemed to anticipate the instant claims.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

QM

/Michele Flood/

Primary Examiner, Art Unit 1655